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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/828,838	KLADAKIS ET AL.	
	Examiner	Art Unit	
	Cherie M. Woodward	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *29-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. ____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/22/04,7/26/05,09/09/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. ____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: ____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I (claims 1-28) in the reply filed on 31 January 2007 is acknowledged. The traversal is on the ground that a single search would suffice for all aspects of the application. This is not found persuasive because Group I (device) and Group II (method of using) are independent and distinct inventions, as discussed in the Requirement for Restriction/Election, mailed 8 January 2007. The restriction under MPEP 806.05(h) between a product and the process of using the product is proper.

Applicant is reminded that where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

2. The information disclosure statements (IDS) submitted on 22 September 2004, 26 July 2005, and 9 September 2005 have been considered. Signed copies are attached hereto. Documents that have been lined through in the 26 July 2005 and 22 September 2004 submissions were documents in various non-English languages and no translation was provided. The documents will be considered when and if certified translations are provided. Additionally, the US Patent documents in the submission of 26 July 2005 have been considered. However, it is noted that US Patents 206,200, 224,226, and 259,260 represent US Patents to a fountain pen-holder, a coal-oil chandelier, and a process of manufacture of indigo-blue, respectively. The relevance of these patents to the present invention is unclear and confusing. If Applicant believes these submissions to be in error, Applicant is encouraged to submit the appropriate references to be considered on a future IDS submission.

Claim Objections

3. Claim 1 is objected to because of the following informalities: the unit of measurement "MPa" is recited in claim 1 as "MPA". Appropriate correction is requested.

Claim Rejections - 35 USC § 112, First Paragraph

Scope of Enablement

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nonwoven biodegradable, biocompatible tissue repair scaffold consisting of 65/35 PGA/PCL foam component mated with a PDS nonwoven polymer having a density of 60mg/cc and a thickness of 1mm with a modulus of elasticity of greater than about 1.5 MPa and a suture pull-out strength of greater than about 6N, prior to implantation (i.e. time zero), does not reasonably provide enablement for the claimed genus of biocompatible tissue repair scaffolds comprising a generic nonwoven polymeric biodegradable material. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability, 5) existence of working samples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The claims are drawn to a biocompatible meniscal repair device comprising a nonwoven polymeric material. The nature of the invention is drawn to a nonwoven, biocompatible, biodegradable polymeric material for use in tissue repair.

The state of the art discloses biodegradable and biocompatible, porous, reinforced tissue repair implants and scaffolds for the use and repair and/or regeneration of diseased or damaged tissue. For example, EP 1216718 A1 (26 June 2002, cited in Applicant's IDS of 9 September 2005) teaches reinforced foam implants for soft tissue repair and regeneration using woven and knitted scaffolds. EP 1405649 A1 (7 April 2004, cited in Applicant's IDS of 9 September 2005) teaches composite woven and knitted scaffolds seeded with mammalian cells. Bowman et al., (U.S. Pregrant Publication US 2002/0127265, 12 September 2002) teaches that the reinforcing component of the scaffold can be non-woven material and the fibers used to make the reinforcing material can be made of biocompatible and biodegradable materials such as polydioxanone (p. 4, paragraph 38), 90/10 polyglycolide-polylactide (PGA/PCL) (p. 7, paragraph 66). Nonwoven fibrous fabric produced by electrospinning is taught at p. 8, paragraph 74; and Example 4, pp. 10-11, paragraphs 106-110 (for background on electrospinning of non-

woven scaffold polymers see, Boland et al., J Macromol Sci –Pure Appl Chem. 2001;A38(12):1231-1243). The level of skill of those in the art is high and requires knowledge of combinatorial polymeric chemistry, biochemistry, physiology, and biomechanics.

The specification discloses one working model of a biocompatible tissue repair scaffold comprising a nonwoven polymeric material. Although working models are not required, they are helpful in determining how to make and/or use Applicant's invention. A 65/35 PGA/PCL foam component mated with a PDS nonwoven polymer having a density of 60mg/cc and a thickness of 1mm with a modulus of elasticity of greater than about 1.5 MPa and a suture pull-out strength of greater than about 6N, prior to implantation is taught at p.20, paragraph 88; and Figures 6A and 6B. However, Figures 6A and 6B show very clearly that the modulus of elasticity and suture pull-out strength of this working model is only valid at time zero. This makes sense because PGA/PCL foam and a nonwoven component comprising PDS are all biodegradable polymers. Thus over time, the components of the scaffold will degrade and will loose both elasticity and tensile strength. This is demonstrated by the comparison of the bar graphs in Figures 6A and 6B, showing that there is significant elasticity and strength degradation after two weeks. The time-dependent degradation shown in Figures 6A and 6B render meaningless the claim limitations of modulus of elasticity and suture pull-out strength, as written. Simply put, Applicant's invention changes over time because of the biodegradability of its component polymers. As such, the claims can only be examined based on physical properties of the composition that are not affected by biodegradation.

With regard to the polymeric material of claim 1 and the genus of polymers comprising glycolides, lactines, caprolactones, trimethylene carbonate, polyvinyl alcohol, and dioxanone of claim 10, the art teaches that the ratio of these polymers in the nonwoven polymeric material is critical to the invention. For example, Boland et al., *supra*, teach that the tensile strength of a polymeric material is entirely dependent on the concentration of the polymer comprising the composition (pp. 1240, Chart 3; p. 1241, Chart 4, paragraph two, and Chart 5). Bowman et al., *supra*, teaches that the reinforcing component of the scaffold can be non-woven material and the fibers used to make the reinforcing material can be made of biocompatible and biodegradable materials such as polydioxanone (p. 4, paragraph 38), 90/10 PGA/PCL (p. 7, paragraph 66). Bowman et al., *supra*, also teach copolymers of polycaprolactone-polyglicolide, from about 35/65 to about 65/35 and polylactide-polycaprolactone from about 35/65 to about 65/35 (p. 3, paragraph 32). Additionally, without knowing the ratio or concentration of any given polymer in the composition one would not be able to make or use a composition comprising one of the recited polymers.

Regarding the bioactive substances of claims 13 and 14, Applicant has failed to recite sufficient guidance as to how to make or use the claimed composition comprising bioactive substances. Applicant discloses a laundry list of possible bioactive substances that can be added to the composition (see specification paragraphs 69-80). Applicant also discloses that "one skilled in the art can readily determine the appropriate quantity of bioactive agent to include within a biocompatible scaffold for a given application in order to facilitate and/or expedite the healing of tissue. The amount of bioactive agent will, of course, vary depending upon the identity of the bioactive agent and the given application" (paragraph 83). Applicant's disclosure in this regard is insufficient to instruct a person of ordinary skill in the art on how to make or use the claimed biocompatible repair scaffold further comprising bioactive substances and amounts only to an invitation for further experimentation.

Regarding claims 17 and 18, it is old and well known in the art that Hooke's law relating to the mechanics of materials (circa 1660) applies to thermoset polymers, where by definition the material properties are independent of direction (see also definition of "isotropic" American Heritage Dictionary. Fourth Ed. 2000). Such materials have only two independent variables, (i.e. elastic constraints) in their stiffness and compliance matrices, as opposed to the 21 elastic constraints in the general anisotropic case (see also, Bowman et al., *supra*, p.7 paragraph 64, which states that it is assumed the reinforcement material will be isotropic and provides guidance for what to do in the event of anisotropy).

Due to the large quantity of experimentation necessary to determine the concentration of any of the various polymers, the composition of the nonwoven polymeric material, and the additional bioactive substances to be added, the lack of direction/guidance presented in the specification regarding same, the absence of sufficient working examples directed to same, the complex nature of the invention, the state of the prior art establishing that the tensile strength of a polymeric material is entirely dependent on the concentration of the polymer comprising the composition, and the breadth of the claims which fail to recite specific polymer compositions, specific polymer concentrations, or specific bioactive substances to be added, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Claim Rejections - 35 USC § 112, First Paragraph

Written Description

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This is a written description rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

The claims are drawn to a biocompatible meniscal repair device comprising a nonwoven polymeric material.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, states that Applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the written description inquiry, is whatever is now claimed (see page 1117). A review of the language of the claim indicates that these claims are drawn to a genus, i.e., biocompatible scaffolds comprising nonwoven polymeric material.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof.

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In *Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that, while applicants are not required to disclose every species encompassed by a genus, the description of the genus is achieved by the recitation of a representative number of species falling within the scope of the claimed genus. At section B(1), the court states, "An adequate written description of a DNA ... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention."

There is a single species of the claimed genus disclosed that is within the scope of the claimed genus, *i.e.* 65/35 PGA/PCL foam component mated with a PDS nonwoven having a density of 60mg/cc and a thickness of 1mm (p.20, paragraph 88; and Figures 6A and 6B). The disclosure of a single disclosed species may provide an adequate written description of a genus when the species disclosed is representative of the genus. However, the present claim encompasses numerous species that are not further described.

The genus of biocompatible scaffolds comprising nonwoven polymeric material are not adequately described in the specification such that one of skill in the art would be apprised that Applicant was in possession of the genus. Although claim 1 recited limitations as to the modulus of elasticity and suture pull-out strength (tensile strength), these parameters will vary in any biodegradable polymeric composition as a factor of time and depending on the concentration of the polymer comprising the composition. See, for example, Applicant's Figures 6A and 6B, which show significantly different maximum load (suture pull-out/tensile strength) and different stiffness (modulus of elasticity) in Figures 6A and 6B over a period of 2 weeks. Additionally, it is well known in the art that tensile strength is dependent on the concentration of the polymer comprising the composition (see, for exemplary purposes only, Boland et al., supra, pp. 1240, Chart 3; p. 1241, Chart 4, paragraph two, and Chart 5).

In the absence of sufficient recitation of distinguishing characteristics, the specification does not provide adequate written description of the claimed genus, which is biocompatible scaffold comprising nonwoven polymeric material. One of skill in the art would not recognize from the disclosure that the applicant was in possession of the genus. The specification does not clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed (see *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-8, 10-15, 17 and 18 are rejected under 35 U.S.C. 102(b) as anticipated by Bowman et al. (U.S. Pregrant Publication US 2002/0127265, 12 September 2002), as exemplified by Boland et al., (J Macromol Sci –Pure Appl Chem. 2001;A38(12):1231-1243).

The claims are drawn to a biocompatible meniscal repair device comprising a nonwoven polymeric material.

Bowman et al., teach a biodegradable and biocompatible, porous, reinforced tissue repair stimulating implant or scaffold for the use and repair and/or regeneration of diseased or damaged tissue including the meniscus (p. 1, paragraphs 10 and 14) (see instant claim 1). Scaffold thickness in the range of about 0.5mm to 1.5mm is taught at p. 8, paragraph 75 (see instant claim 1). The scaffold comprising a bioabsorbable polymeric foam having pores with an open cell structure that is joined or reinforced by a material to contribute enhanced mechanical and handling properties is taught at p.2, paragraph 23 and p. 4, paragraph 42 (see instant claim 6). Non-woven biocompatible bioabsorbable reinforcing material is taught at p. 4, paragraph 38 (see instant claim 8). Nonwoven reinforcing material comprising synthetic polymeric blends of polylactides and glycolides are taught at pp. 2-3, paragraph 28; and p. 4, paragraph 40 (see instant claims 7, 10, and 12). Copolymers of polycaprolactone-polyglicolide, from about 35/65 to about 65/35 and polylactide-polycaprolactone from about 35/65 to about 65/35 are taught at p. 3, paragraph 32 (see instant claims 7 and 10). The reinforcing component of the scaffold can be a non-woven material and the fibers used to make the reinforcing material can be made of biocompatible and biodegradable materials such as polydioxanone (p. 4, paragraph 38) (see instant claim 11), 90/10 polyglycolide-polylactide (p. 7, paragraph 66) (see instant claims 10 and 12). Nonwoven fibrous fabric produced by electrospinning is taught at p. 8, paragraph 74; and Example 4, pp. 10-11, paragraphs 106-110 (for background on electrospinning of nonwoven biocompatible scaffold polymers see generally, for exemplary purposes only, Boland et al., pp. 1231-1243). The ability to align fibers or orient fibers randomly (meeting the definition of isotropic in instant claim 18) are both inherent processes of electrospinning (see, for exemplary purposes only, Boland et al., supra, at p. 1238, paragraphs three and four, and especially p. 1239, Figure 4) (see also, for exemplary purposes only, the definition of "isotropic" American Heritage Dictionary. Fourth Ed. 2000) (see instant claim 18). Addition of a bioactive substance such as cartilage derived morphogenic proteins, which belong to the TGFβ family, some of which are known as bone morphogenic proteins, and platelet-derived growth factor (PDGF) are taught at pp. 4-5, paragraph 43 (see instant claims 13 and 14). PDGF is an inherent component of platelet-rich plasma, which is a concentrate of platelets in a small volume of plasma and therefore concentrate of the 3 isomers of PDGF (PDGFαα, PDGFββ and PDGFαβ) (see, for exemplary purposes

only Tozum et al., J Canadian Dental Assoc. 2003 Nov. 69(10):664-664h). Therefore, by incorporating platelet-rich plasma into a scaffold implant, one must incorporate PDGF. The addition of cells to the scaffold, such as chondrocytes are taught at p. 5, paragraph 47; and p. 11, Example 6. Bowman et al., teach that tendon or ligament ends can be joined (e.g., by suturing, stapling, clipping, adhering, or anchoring) to ends of the implant, (paragraph 80) (compare instant claim 15). Bowman et al., teach heat pressing the nonwoven polymeric material prior to its placement within the mold in order to ensure the proper degree of flatness (paragraph 64) (compare instant claim 17).

Although claim 1 recited limitations as to the modulus of elasticity and suture pull-out strength (tensile strength), these parameters will vary in any biodegradable polymeric composition as a factor of time and depending on the concentration of the polymer comprising the composition. See, for example, instant Figures 6A and 6B, which show significantly different maximum load (suture pull-out/tensile strength) and different stiffness (modulus of elasticity) in Figures 6A and 6B over a period of 2 weeks. While the reference does not explicitly teach the specific modulus of elasticity or suture pull-out strength (also known as tensile strength) of the claimed scaffold, case law has established that the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Additionally, it is well known in the art that tensile strength is dependent on the concentration of the polymer comprising the composition (see, for exemplary purposes only, Boland et al., supra, pp. 1240, Chart 3; p. 1241, Chart 4, paragraph two, and Chart 5). Therefore, absent evidence to the contrary, the prior art discloses exactly what is claimed in the instant application.

Additionally, case law recognizes that a compound and all of its properties are inseparable (In re Papesch, 315 F.2d 381, 137 USPQ 43 (CCPA 1963)). The time-dependent degradation of biodegradable biocompatible polymers shown in Figures 6A and 6B of the instant specification render meaningless the instant claim limitations of modulus of elasticity and suture pull-out strength (see instant claims 1-4). Simply put, Applicant's invention changes over time because of the biodegradability of its component polymers. As such, the claims can only be examined based on physical properties of the composition that are not affected by biodegradation.

Further, because the Patent Office does not have the facilities to determine whether the scaffold of claim 1 has the requisite modulus of elasticity or suture pull-out strength, the burden is on the application to show a novel and unobvious difference between the claimed scaffold and that of the prior art. See In re Brown, 59 CCPA 1036, 459 F.2d. 531, 173 USPQ 685 (CCPA 1972) (holding at 1041,

"[a]s a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith") and Ex parte Gray, 10 USPQ 2d 1922, 1924-25 (PTO Bd. Pat. App. & Int.).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 1-28 are rejected under 35 U.S.C. 103(a) as being obvious over Bowman et al. (U.S. Pregrant Publication US 2002/0127265, 12 September 2002), as exemplified by Boland et al., (J Macromol Sci –Pure Appl Chem. 2001;A38(12):1231-1243), in view of Huckle et al., WO 01/85226 (published 15 November 2001).

Bowman et al., teach as stated *supra*. Bowman et al., do not teach a dry-laid nonwoven polymeric material. Claim 9 is drawn to a nonwoven polymeric material produced by a dry lay process. It is noted that although claim 9 is a product-by-process claim, it is being treated as an obvious variant of the scaffold taught by Bowman et al., because although the physical properties of the compositions produced by a dry laid process versus a wet laid process are equivalent, they are not necessarily identical. See In re Marosi, 710 F.2d 799, 218 USPQ 289 (Fed. Cir. 1983) and In re Thorpe, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). See also MPEP § 2113.

Huckle et al., teach tissue scaffolds fashioned from nonwoven material that can be bioresorbable or nonbioresorbable (p. 3, lines 30-34; p. 9, lines 29-31) (see instant claims 1 and 25). Huckle et al., also teach tissue scaffolds comprising a nonwoven fibrous material, a foam, or a mixture of nonwoven and foam (p. 9, last paragraph) (see instant claims 1 and 19). The thickness of the scaffold between 0.25 to 5

mm thick is taught at p. 11, lines 30-31 (see instant claim 23). Synthetic polymers comprising polylactides, polyglycolides, and polydioxanone are taught at p. 8, lines 34-35 (see also, p. 3, last paragraph to p. 4, first paragraph) (see instant claim 24). Dry laid nonwoven material is taught at p. 11, lines 25 (see instant claim 9). Random entanglement is taught as providing a large surface area for cell attachment or capture during cellular in-growth (p. 11, lines 26-27). Example 7, pp. 20-23, teach dry laid nonwoven yarn produced by feeding it into a stuffer box type crimping unit (p. 20, line 35 to p. 21, first paragraph) (see instant claim 16). Example 7 also teaches heat-setting at p. 21, third and fourth paragraphs (see instant claim 17). Example 5 (p. 20) teaches implanting scaffold over a menicus (see also p. 4, second paragraph) (see instant claims 1 and 19). Scaffolds comprising cells and tissue are taught at Examples 5 and 6, p. 20) (see instant claims 15 and 28). Tissue grafts are also taught at p. 5, first paragraph. The inclusion of biological molecules such as TGF, BMP, CDMP, and PDGF are taught at p. 4, third paragraph (see instant claims 26 and 27).

It would have been prima facie obvious to the person of ordinary skill in the art at the time the invention was made to combine the teachings of Bowman et al., and Huckle et al., to produce a biocompatible scaffold comprising a nonwoven polymeric material from either wet laid (i.e. electrospray) or dry laid polymer in order to reinforce a foam scaffold where the combined foam and nonwoven scaffold provides increased suture-pull out strength. The person of ordinary skill in the art would have been motivated to make those modifications because bioabsorbable polymeric foams that are reinforced by a nonwoven material produce a stronger implant that contribute enhanced mechanical and handling properties of the implant, thus allowing increased support for the implant while the patient is healing. Additionally, Huckle et al., teach that random entanglement in the nonwoven scaffold provides a large surface area for cell attachment or capture during cellular in-growth. One of skill in the art reasonably would have expected success because Huckle et al., teach nonwoven scaffolds used in conjunction with foams to provide superior strength for the implant. The methods of producing the nonwoven components, whether by a wet lay process (i.e. electrospinning) or by a dry laid process, are taught as equivalents by Huckle et al., and thus, one would reasonably expect to produce a strong scaffold using either or both processes.

Although claims 1-4 and 19-22 recite limitations as to the modulus of elasticity and suture pull-out strength (tensile strength), these parameters will vary in any biodegradable polymeric composition as a factor of time and depending on the concentration of the polymer comprising the composition. See, for example, instant Figures 6A and 6B, which show significantly different maximum load (suture pull-out/tensile strength) and different stiffness (modulus of elasticity) in Figures 6A and 6B over a period of 2

weeks. While the reference does not explicitly teach the specific modulus of elasticity or suture pull-out strength (also known as tensile strength) of the claimed scaffold, case law has established that the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Additionally, it is well known in the art that tensile strength is dependent on the concentration of the polymer comprising the composition (see, for exemplary purposes only, Boland et al., supra, pp. 1240, Chart 3; p. 1241, Chart 4, paragraph two, and Chart 5). Therefore, absent evidence to the contrary, the prior art discloses exactly what is claimed in the instant application.

Additionally, case law recognizes that a compound and all of its properties are inseparable (In re Papesch, 315 F.2d 381, 137 USPQ 43 (CCPA 1963)). The time-dependent degradation of biodegradable biocompatible polymers shown in Figures 6A and 6B of the instant specification render meaningless the instant claim limitations of modulus of elasticity and suture pull-out strength (see instant claims 1-4). Simply put, Applicant's invention changes over time because of the biodegradability of its component polymers. As such, the claims can only be examined based on physical properties of the composition that are not affected by biodegradation.

Conclusion

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cherie M. Woodward whose telephone number is (571) 272-3329. The examiner can normally be reached on Monday - Friday 9:00am-5:30pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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